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13 February 2019

US EPA Office of Pollution Prevention and Toxics
EPA East Building - Room 6428 - Attn: Section 8(e)
1201 Constitution Avenue, NW
Washington, DC 20004-3302

Return Receipt Requested

SUBJECT: TSCA 8(e) Notice

United Initiators, Inc.
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Dear TSCA Section 8(e) Coordinator:

On behalf of the study sponsor named below I am submitting an update to the interim results of the currently on-going extended one-generation reproductive toxicity study (EOGRTS, OECD 443) with Tert-butyl-2-ethylperoxyhexanoate (CAS# 3006-82-4, our product notation TBPEH). This is an update to the previously reported interim results of 11 November 2018. The study sponsor is United Initiators GmbH & Co. KG.

Study details:

Reference: report plan no. 552-443-3843

Performed by: Toxi-Coop ZRT, Hungary

Additional Interim Results of P0 and F1 (Cohort 1A and Cohort 1B) generation:

Oral treatment of male and female Han:Wistar rat (of Wistar origin) at the dose levels of 100, 300, and 1000 mg/kg bw/d for ten weeks pre-mating period, during mating and post-mating period as well as their progeny revealed the following effects (as far as evaluated until 13 February 2019):

- Hematology: Mean values of all parameters examined were all comparable in the control and the test item treated groups at all dose levels, in the P0 as well as F1 (Cohort 1A) generation in both sexes, i. e. none of the parameters revealed statistical significance when compared to the control.
- Clinical chemistry: Mean values of all parameters examined were all comparable in the control and the test item treated groups at all dose levels, in the P0 as well as F1 (Cohort 1A) generation in both sexes, i. e. none of the parameters revealed statistical significance when compared to the control.
- Fertility F1 Cohort 1B:
The mating, fertilization and pregnancy were considered successful/normal in the control, 100 and 300 mg/kg bw/day. At the 1000 mg/kg bw/day:
 - o 9 pregnant females, 8 mated females are non-pregnant
 - o 2 females had prolonged mating period, one other did not mate - even with changed males.
 - o Two male animals at 1000 mg/kg bw/day did not mate during the two weeks period.
 - o The non-pregnant females had no implantation sites and no corpora lutea at necropsy

- Histopathological examination of the P0 animals obtained the following findings (preliminary, not audited yet):

Table 1 Summary incidence of all histopathological findings (%); Males of P0 generation

HISTOPATHOLOGICAL FINDINGS PER ORGANS	GROUPS (mg/kg bw/day)	0	100	300
TESTES:	- active spermatogenesis	100	/	/
EPIDIDYMIDES:	- storage of mature spermatozoa	100	/	/
SEMINAL VESICLE:	- decreased amount of secrete (one side)	4,16	0	/
STOMACH:	- congestion	0	8,33	4,16
	- erosion	0	4,16	
KIDNEY:	- pyelectesis	8,35	4,16	4,16
	- chronic progressive nephropathy (CPN)	20,83	0	/
ABDOMINAL CAVITY:	- lipoma	0	12,50	/
LUNG:	- alveolar emphysema	4,16	/	0

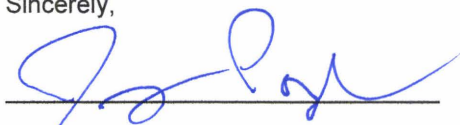
Table 2 Summary incidence of all histopathological findings (%); Females of P0 generation

HISTOPATHOLOGICAL FINDINGS PER ORGANS	GROUPS (mg/kg bw/day)	0	100	300
OVARIES:	- primordial, secondary and tertiary follicles	100	/	100
	- corpora lutea	100	/	100
	- cyst	4,16	/	0
	- decrease in the number of developing follicles	0	/	0
	- increase in the number of follicular atresia	0	/	0
UTERUS:	- dilatation	29,16	20,83	16,66
	- abscess	0	0	4,16
STOMACH:	- congestion	8,33	41,66	33,33
	- erosion	0	12,20	33,33
KIDNEY:	- pyelectasia	0	16,66	16,66
	- chronic progressive nephropathy (CPN)	0	0	0

This submission is not considered to be confidential. The item of concern is on the public list.

Please contact me at (440) 326-2429 if you have any questions regarding this letter.

Sincerely,



Jeremy Pogorelec

Chemist

Cc: Nouryon
Arkema France

Pergan GmbH
United Initiators GmbH & Co. KG



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